

Atty Dkt. No.: SMAR-020
USSN: 10/057,846

REMARKS

In view of the following remarks, the Examiner is respectfully requested to withdraw the rejections and allow Claims 1-15, 17, 20, 40-44, 46 and 51-54, the only claims pending and under examination in this application.

The claims have been amended to remove the element "NR3+." This amendment has been made solely in order to expedite allowance of the present application. In no way should this amendment be construed as an acquiescence by the Applicants with the position asserted by the Office in the Final Rejection. Furthermore, the Applicants note that this amendment does not alter the scope of the claims, as the claims include pharmaceutically acceptable salts of the recited compounds. In addition, Claims 17 and 42 have been amended to correct a typographical error with respect to substituent R. Claim 18 has also been canceled. The Examiner is thanked for the acknowledgement of the allowability of the subject matter of Claim 20. As the above amendments introduce no new matter to the application, their entry by the Examiner is respectfully requested.

Claim Rejections under 35 U.S.C. § 112, first paragraph

The Examiner has maintained the rejection of claims 40-44 and 46 under 35 U.S.C. §112 first paragraph as assertedly failing to comply with the enablement requirement.

In maintaining this rejection, the Examiner continues to assert that the claims are directed to methods of treating cancer and that the Applicants have failed to enable methods of treating cancer.

The Applicants again point out that the claims are directed to methods of

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inhibiting **cellular invasion** or **angiogenesis**. For example, Claim 40 reads in part:

" A method for inhibiting cellular invasion or angiogenesis in a patient in need thereof..."

One of skill in the art reading the term "cellular invasion" in view of the teaching of the specification would clearly know that the term "cellular invasion" refers to the movement of cell from a first bodily location to a second bodily location. See e.g., the specification at page 1, lines 9 to page 2, line 5, and the use of the term "cellular invasion," therein.

In support of these claims, the Applicants provide working exemplification showing the cellular invasion inhibitory activity of representative compounds, as measured by an improved version of art accepted assays of cellular invasion modulatory activity. Specifically, the assay of cellular invasion that was used to test the activity of representative compounds is described at page 17, line 5 ff. The results are reported at page 23, line 1 ff, where all of the tested compounds inhibited cellular invasion, as measured by the employed cellular invasion assay.

Because the inventors have provided working exemplification showing the cellular invasive activity of multiple representative compounds in a cellular invasion assay, they have enabled methods of inhibiting cellular invasion.

With respect to methods of inhibiting angiogenesis, one of skill in the art would know that the term angiogenesis as used in the claims has its art accepted definition of the formation of new blood vessels.

In support of these claims, the Applicants provide working exemplification showing the anti-angiogenic activity of representative compounds, as measured by art accepted in vitro and in vivo assays. Specifically, the assays of angiogenic activity that were used to test the activity of a representative compound is described at page 25, line

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25 to page 26, line 26. The results are reported at page 26, line 1 ff, where all of the tested compounds inhibited cellular invasion, as measured by the employed in vitro and in vivo assays.

Because the inventors have provided working exemplification showing the anti-angiogenic activity of a representative compound in art accepted assays of anti-angiogenic activity, they have enabled methods of angiogenesis.

It is again noted that the enablement requirement under 35. U.S.C. §112, first paragraph requires that the "disclosure is sufficient to enable one of skill in the art to carry out the invention commensurate with the scope of the claims" (Amgen v. Chugai (1991) 18 USPQ 2d 1016 at 1027). To be enabled a specification should contain "sufficient information regarding the subject matter of the claims as to enable one skilled in the pertinent art to make and use the claimed invention" (MPEP 2164.01 p. 2100-179).

As detailed above, the claims clearly recite inhibition of cellular invasion and angiogenesis. The specification clearly teaches inhibition of cellular invasion and angiogenesis by numerous compounds falling within the scope of the claims in a variety of different assays and in a variety of cell types, both in vitro and in vivo (p. 23-28). Accordingly, the Applicants respectfully submit that the present claims are enabled.

In view of the above, it is respectfully submitted that claims 40-44 and 46 are fully enabled by the specification and that this rejection under 35 U.S.C. §112, first paragraph may be withdrawn.

Claim Rejections under 35 U.S.C. § 112, second paragraph

Claims 1-15, 17, 40-44, 46 and 51-54 have been rejected under 35 U.S.C. § 112,

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second paragraph for separately identified issues (a) and (b). Each of these issues is separately addressed below.

(a). In view of the amendments to the claims, this issue has been addressed.

(b). Finally, with respect to the phrase "cellular invasion" it is submitted that when this phrase is read in view of the specification, see the assays described beginning at page 14, lines 25 ff, it is clear that what is meant by "cellular invasion" is invasion by a cell of other parts of a body, and not invasion of an agent into a cell.

In view of the above remarks, the rejection of Claims 1-15, 17, 40-44, 46 and 51-54 under 35 U.S.C. § 112, second paragraph may be withdrawn.

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CONCLUSION

In view of the above remarks, this application is considered to be in good and proper form for allowance and the Examiner is respectfully requested to pass this application to issuance.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815.

Respectfully submitted,
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